

<u>UNITED STATES PATENT AND TRADEMARK OFFICE</u>

Examiner: K. McMILLAN

Art Unit: 1614

Re:

Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

SYNERGISTIC ANALGESIC COMBINATION

OF OPIOID ANALGESIC AND

CYCLOOXYGENASE-2 INHIBITOR

INFORMATION DISCLOSURE STATEMENT NO. 3

Assistant Commissioner for Patents Washington, D.C. 20231

June 7, 1999

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is

The references cited on the enclosed PTO-1449 Form relate to compounds described as being useful in the treatment of cyclooxygenase-2 mediated disease states. Reference 'AM' is cited for its discussion of COX-2 and COX-1 activity.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 7, 1999.

DAVIDSON, DAVIDSON & KAPPEL, LLC

By Jacquelie Cevarder

The Examiner's particular attention is directed to U.S. Patents No. 5,409,944 and 5,436,265, referenced on the enclosed PTO-1449 Form as 'AA,' and 'AB.' These patents describe, inter alia, compounds with cyclooxygenase-2 inhibitory properties in combination with "antitussives including codeine, hydrocodone, caramiphen, carbetapentane or dextromethorphan." (See column 6, lines 33-35 of the '944 patent, and column 5, lines 48-50 of the '265 patent). The Examiner's attention is also directed to U.S. Patent No. 5,521,213, referenced on the enclosed PTO-1449 Form as 'AD.' This patent discloses, inter alia, "[a compound for treating cyclooxygenase-2 mediated diseases] and one or more ingredients such as another pain reliever including acetaminophen or phenacetin . . . an antitussive including codeine, hydrocodone, caramiphen, carbetapentane or dextromethorphan " (See column 6, lines 7-15). A similar disclosure is also found in U.S. Patent No. 5,550,142 referenced on the enclosed PTO-1449 Form as 'AE,' at column 7, line 56 - column 8, line 5, U.S. Patent. 5,552,422, referenced on the enclosed PTO-1449 Form as 'AF,' at column 9, line 59 - column 10, line 7, U.S. Patent 5,604,253, referenced on the enclosed PTO-1449 Form as 'AG,' at column 10 line 66 - column 11, line 14, and U.S. patent 5,639,780, referenced on the enclosed PTO-1449 Form as 'AH,' at column 11, lines 36-51.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

February 4, 2000

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Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form describe various COX-2 inhibitors, including 4-[4-(methylsulfonyl)phenyl]-3-phenyl-2(5H)-furanone (rofecoxib), the elected species set forth in the claims as amended.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on February 4, 2000.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: Aut /

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The references further describe the COX-2 inhibitors described therein in combination with "one or more ingredients such as another pain reliever including acetaminophen or phenacetin;...[and] an antitussive including codeine, hydrocodone," (See column 8 of the '955 patent, and column 13 of the '374 patent). This is the same discussion included in other patents assigned to Merck Frosst Canada Inc., which was previously pointed out to the Examiner in the Information Disclosure Statement filed June 7, 1999. Oxycodone is not included in this discussion.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

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